

MAZIE SLATER KATZ & FREEMAN, LLC

103 Eisenhower Parkway, Suite 207, Roseland, NJ 07068

Phone: (973) 228-9898 - Fax: (973) 228-0303

www.mazieslater.com

David A. Mazie*
Adam M. Slater*^o
Eric D. Katz*^o
David M. Freeman
Beth G. Baldinger
Matthew R. Mendelsohn^o
David M. Estes

*Certified by the Supreme Court of
New Jersey as a Civil Trial Attorney

Karen G. Kelsen^o
Cheryll A. Calderon
Adam M. Epstein^o
Cory J. Rothbort*^o
Michael R. Griffith^o
Christopher J. Geddis
Samuel G. Wildman
Julia S. Slater^o

^oMember of N.J. & N.Y. Bars

May 17, 2021

VIA ECF and EMAIL

Honorable Thomas I. Vanaskie (Ret.)
Special Master
Stevens & Lee
1500 Market St., East Tower, Suite 1800
Philadelphia, Pennsylvania 19103-7360

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation,***
Case No. 1:19-md-02875-RBK (D.N.J.)

Dear Judge Vanaskie:

Please accept this letter on behalf of Plaintiffs in reply to ZHP's opposition to Plaintiffs' request for production of Baohua Chen's custodial file.¹

On April 27, 2021, Plaintiffs filed an application seeking to compel ZHP to produce Baohua Chen's custodial file, detailing his substantive role at ZHP as the linchpin for more than a dozen of its departments and "subsidiaries." ([ECF 1189](#)). As demonstrated (and contrary to ZHP's mantra that he was a mere figurehead apex executive), this included direct involvement in ZHP's

¹ ZHP also filed a cross motion for a protective order precluding the production of the custodial file of Baohua Chen, and requested oral argument. ([ECF 1246](#)). The Court did not grant ZHP leave to file such a duplicative cross motion, and it should be disregarded accordingly. ([ECF 1217](#)).

Honorable Thomas I. Vanaskie (Ret.)
May 17, 2021
Page 2

development of the contaminating zinc chloride manufacturing process in 2011, and his leadership of the Valsartan “Recall Group,” among other examples. *Id.* On May 3, 2021, the Court agreed, stating, “Based upon what's been presented to me thus far, it seems to me that he would have unique material information and had an involvement beyond that which has been described thus far,” concluding “I am inclined to order the production of Mr. Chen's custodial file.” [Tr. 27:14-15, 17-20](#). Generally speaking, ZHP concedes that Mr. Chen is ZHP’s “General Manager.” At no point does ZHP establish the Mr. Chen does not hold actionable knowledge, instead deflecting to self-serving testimony from Mr. Chen’s employees and arguments that mischaracterize and are not faithful to the record.

ZHP’s opposition fails to contend with the record establishing the relevance and need for discovery from Mr. Chen. This includes representations in official regulatory filings. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] ZHP fails to grapple with the fact that its own documents clearly point to Mr. Chen’s substantive role. ZHP’s apparent argument that Plaintiffs have not relied on enough documents involving Mr. Chen to warrant the production

Honorable Thomas I. Vanaskie (Ret.)
May 17, 2021
Page 3

of his custodial file is not an answer to what has been presented, and simply speaks to the Plaintiffs' need for the custodial file to have a more fulsome picture of his involvement.

A. ZHP Misrepresents Its Production Relating to Baohua Chen

ZHP claims that "only about 375 [documents] constitute correspondence with Mr. Chen." (ZHP's Opp. Br. 7). In fact, a simple search of the ZHP Defendants' production using Mr. Chen's email address pulls 690 documents. This is pointed out simply to show that ZHP is not accurately portraying the status of the production. Of course, the number of documents is not determinative, and as the Court is well aware, the revelation of just a few documents can have a significant impact on the litigation (see discussion of the July 27, 2017 email below). Most important, we do not yet have Mr. Chen's custodial file, which is the key fundamental documentary discovery needed, to be followed by his deposition.

B. ZHP Misrepresents the Import of the July 27, 2017 Email

ZHP attempts to deflect the Court's appreciation of the significance of this email. ZHP inexplicably emphasizes that Plaintiffs have had this email since September 20, 2020, in a classic effort to deflect attention from the true issue. (ZHP's Opp. Br. 8). **What matters is the substance of the email –** [REDACTED]

[REDACTED]

[REDACTED]

The email states, according to the ZHP supplied translation, which is slightly different from the translation confirmed during the deposition of Min Li:

[REDACTED]

Honorable Thomas I. Vanaskie (Ret.)

May 17, 2021

Page 4

[REDACTED]

[REDACTED]

[REDACTED]

(ZHP Opp. Br., Ex. K). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In the face of this record, ZHP's attempt to deflect blame is troubling and demonstrates the lengths ZHP will go to in an effort to avoid responsibility.

ZHP claims that "[a]ny connection between this email and Mr. Chen is pure conjecture."

(ZHP's Opp. Br. 8). However, the email specifically asks [REDACTED]

[REDACTED]

[REDACTED]

(ZHP01662332, Ex. 1 hereto; *see also* ZHP01633850, Ex. 2 hereto; ZHP01458548, Ex. 3 hereto).

It stands to reason that Mr. Chen should have known about this email, and Plaintiffs are entitled to

Honorable Thomas I. Vanaskie (Ret.)
May 17, 2021
Page 5

review his custodial file to assess the extent to which he knew about it or at the very least knew that nitrosamine contaminants were a [REDACTED]

[REDACTED]. Moreover, if ZHP is correct that Mr. Chen's custodial file does not reflect a documented communication to Mr. Chen about this email, that does not help ZHP's cause, since that would mean that the likely communications were not documented. In either case, Plaintiffs are entitled to the fullest picture possible in approaching the upcoming deposition of Mr. Chen, and production of his custodial file is an important piece of that picture.

C. Plaintiffs Are Not Seeking to Engage in a Fishing Expedition

After reviewing Plaintiffs' April 27, 2021 letter, the Court has concluded that "[b]ased upon what's been presented to me thus far, it seems to me that he would have unique material information and had an involvement beyond that which has been described thus far." [5/3/2021 Tr. 27:17-20](#). Thus, ZHP's claims that Mr. Chen's numerous meetings regarding the development and recall of valsartan "do not demonstrate that [he] would possess any material, non-cumulative, non-duplicative information" has already been rejected. (ZHP's Opp. Br. 14). In light of the documented heavy attention paid by Mr. Chen to the valsartan manufacturing process and the resulting NDMA contamination, including calling and attending numerous meetings, Plaintiffs have the right to production of the custodial file regardless of ZHP's self-serving representation that Mr. Chen did not create and maintain his own documents and files regarding Valsartan. It is worth noting that every department and subsidiary reports directly to Mr. Chen. He is the sole person responsible for synthesizing and orchestrating how these departments and subsidiaries ultimately manufactured and sold ZHP's drugs. [REDACTED]

Honorable Thomas I. Vanaskie (Ret.)
May 17, 2021
Page 6

[REDACTED]

[REDACTED] As the leader of Shanghai Syncores, ZHP's sales department, and ZHP's Quality unit, Mr. Chen was uniquely situated to control and be fully knowledgeable about the key steps along the way. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

ZHP also attempts to minimize Mr. Chen's interaction with regulatory authorities. (ZHP Opp. Br. 15-16). However, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]

[REDACTED]

ZHP claims that despite [REDACTED]

[REDACTED], Mr. Chen does not possess "any uniquely material documents." (ZHP's Opp. Br. 16). This argument is not credible. ZHP relies on Eric Gu's deposition to support this contention, but Mr. Gu only started working at Syncores in 2014, and Syncores finished developing the process in 2011. [REDACTED]

Honorable Thomas I. Vanaskie (Ret.)

May 17, 2021

Page 7

[REDACTED]

[REDACTED] (4/05/2021 Tr. of Dep. of Eric Gu 53:24-54:6, 73:21-74:7, 203:20-204:1, ZHP's Opp. Br., Ex. D). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (ZHP02385482, Ex. 16). [REDACTED]

[REDACTED] This is just another example of a document showing that Mr. Chen is not an apex figurehead – he is and has been an important part of the valsartan story.

ZHP ultimately most heavily relies on self-serving testimony, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (ZHP's Br. 17-18). [REDACTED]

[REDACTED] (4/05/2021 Tr. of Dep. of Eric Gu 117:9-119:2, ZHP's Opp. Br., Ex. D). Moreover, as repeatedly demonstrated, ZHP's own documents refute this testimony. For example, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Honorable Thomas I. Vanaskie (Ret.)

May 17, 2021

Page 8

[REDACTED]

[REDACTED]

[REDACTED]

Honorable Thomas I. Vanaskie (Ret.)

May 17, 2021

Page 9

[REDACTED]

[REDACTED]

[REDACTED]

Honorable Thomas I. Vanaskie (Ret.)

May 17, 2021

Page 10

(ZHP01423197, emphasis added, Ex. 17 hereto). [REDACTED]

[REDACTED]

[REDACTED] (ZHP00292153, Ex. 18 hereto). [REDACTED]

[REDACTED]

[REDACTED] (ZHP00292149, Ex. 18 hereto). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (ZHP02666849, Ex. 28 hereto). [REDACTED]

[REDACTED]

[REDACTED] Plaintiffs have the absolute right to see the contents of the custodial file to see what information was provided, and Mr. Chen's input and work with drafts of the documents. An important component of this case is the communications from ZHP misrepresenting the timing and substance of ZHP's knowledge of the NDMA contamination – and Mr. Chen's involvement and role in this concerted pattern of misrepresentations.

Shortly after the discovery of the nitrosamine contamination, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (TEVA-MDL2875-00611842, Ex. 19 hereto). His involvement was not distant and supervisory – he was engaged and a leader of ZHP's work on this matter.

[REDACTED] [REDACTED]

[REDACTED]

Honorable Thomas I. Vanaskie (Ret.)

May 17, 2021

Page 11

[REDACTED]

[REDACTED] (ZHP01224767 ([REDACTED])

[REDACTED]

[REDACTED]

[REDACTED], Ex. 20 hereto). [REDACTED]

[REDACTED] (See TEVA-

MDL2875-00662718, Ex. 21 hereto; TEVA-MDL2875-00370081, Ex. 22 hereto; ZHP01761094,

Ex. 23 hereto). [REDACTED]

[REDACTED] (ZHP00667853,

Ex. 24 hereto). [REDACTED] (See PRINSTON00468994,

Ex. 25 hereto; ZHP02471924, Ex. 26; ZHP02490581, Ex. 27).

D. ZHP Can Produce Baohua Chen's Custodial File Without Violating Chinese Law

ZHP vaguely claims that “because Mr. Chen uses his ZHP email account in the course of carrying out his public duties, the production of Mr. Chen’s custodial file places Mr. Chen *in jeopardy of violating the Criminal Law and the State Secrets Law of the PRC.*” (ZHP’s Opp. Br. 18 (emphasis added)). This argument is specious, and was never made prior. Plaintiffs are not responsible for Mr. Chen’s use of his business email to conduct alleged government business, and this only goes to whether or to what extent ZHP may attempt to withhold relevant documents from production, which is not a consideration on this motion. Mr. Chen would certainly provide the FDA information on request, and the resistance to doing so in this proceeding is very troubling.

Honorable Thomas I. Vanaskie (Ret.)
May 17, 2021
Page 12

Conclusion

For the foregoing reasons, and those set forth in Plaintiffs' initial submissions, Plaintiffs request that the Court order production of Baohua Chen's custodial file as soon as practicable so that Plaintiffs will have sufficient time to review and utilize the documents and information in the ongoing development of this case. Plaintiffs also request that ZHP's cross-motion for a protective order, filed without leave of Court, be denied.

Respectfully,



ADAM M. SLATER